

**TEXAS STATE BOARD OF PHARMACY
RECOMMENDATIONS FOR LEGISLATIVE ACTION DURING THE 2013 SESSION
PRIORITY ORDER**

- 1. Self-Directed Semi-Independent Agency Status** – Seek legislative authority to become a Self-Directed Semi-Independent Agency.

Background

In 1999 the Texas Legislature passed SB 1438 that established a pilot project to assess the practicality and efficiency of changing certain professional and occupational licensing boards to semi-independent self-directed status. Initially three agencies were a part of the pilot project: The Texas Board of Texas State Board of Public Accountancy; the Texas Board of Professional Engineers; and the Texas Board of Architectural Examiners. The initial pilot was for four years until September 1, 2003. The pilot project was extended in 2003 and in 2007 until 2013. In 2009, the financial regulatory agencies were added to the project. The additional agencies are the Texas Department of Banking; the Department of Savings and Mortgage Lending; the Office of Consumer Credit Commissioner; and the Credit Union Commission for the Credit Union Department.

The budget of these agencies is not set by the Legislature, but is set by the agency's governing Board. The agencies maintain all of the authority over their respective professions and they are subject to the Administrative Procedures and Open Records Act.

2. ALL PASSED IN SECTION 10, 11, AND 9 OF SB 869.

Qualifications for a Pharmacy License or to Renew a Pharmacist's License.

- A. ~~Amend Section 560.052(b) of the Texas Pharmacy Act by adding a paragraph (3) that would require an applicant for a pharmacy license in Texas to "show proof that the current license and any other license granted to the applicant has not been subject to a disciplinary action in any other state that that restricts, suspends, revokes or surrenders the pharmacy license." This language is currently in Section 558.101(a)(4)(B) for pharmacists who are reciprocating their license into Texas.~~
- B. ~~Amend Section 561.003 of the Texas Pharmacy by adding a new subsection (f) that would not allow a pharmacy to renew a Texas pharmacy license if the pharmacy holds a pharmacy license in another state that suspended, revoked, cancelled or otherwise disciplined such that the pharmacy cannot operate in another state.~~
- C. ~~Amend Section 559.003 of the Texas Pharmacy Act to add a new subsection (e) that would prohibit a pharmacist in Texas from renewing their Texas pharmacy license if the pharmacist's license in another state is suspended, revoked, cancelled or otherwise disciplined such that the person cannot practice in another state.~~

3. PASSED IN SECTION 13 OF SB 869.

Pharmacist's Professional Responsibility – ~~Amend Section 562.056(a) of the Pharmacy Act to read the same as Section 483.021(a) of the Texas Dangerous Drug Act and add a new subsection (b) to include the current language regarding a pharmacist's corresponding responsibility when dispensing a controlled substance.~~

- 4. Regulatory Authority over Pharmacist/Technician Relief Services** – Amend the Texas Pharmacy Act to give the Board regulatory authority over pharmacist-relief services.

Background

Currently, there is no regulation of Pharmacist/Technician Relief Services. In the past the agency has had problems obtaining information from these services, including if a pharmacist is working for the service and where a pharmacist is working on any given day.

5. PASSED IN SECTION 16 OF SB 869.

Release of Confidential Investigative Information – ~~Amend Section 565.055(c)(3) of the Pharmacy Act to allow the Board to release information regarding an investigation on pharmacy technicians to an entity in another jurisdiction that registers pharmacy technicians and to an entity that administers a board-approved pharmacy technician certification examination.~~

6. PASSED IN SECTION 5 OF SB 869.

Acceptance of Gifts and Grants—Amend Section 554.007(b) of the Pharmacy Act to allow the Board to receive and spend gifts and grants using language similar to that in Section 301.156 of the Nursing Practices Act.

7. PASSED IN SECTION 14 OF SB 869. However, Section 562.051 needs to be amended to reference the changes made to 562.103

Sec. 562.051. Display of Pharmacist License.

A pharmacist shall publicly display the pharmacist's license to practice pharmacy and license renewal certificate in the pharmacist's primary place of practice, as specified in Section 565.103(b) of this title.

Display of Licenses by Pharmacy—Amend Section 562.103(b) to specify that a pharmacy is not required to post the licenses of pharmacists employed by the pharmacy.

Background

Currently the law requires all Class A and Class C Pharmacies to display the licenses of all pharmacists employed in the pharmacy

8. PASSED IN SECTION 12 OF SB 869.

Substitution of Dosage Forms—Amend Section 562.012 of the Texas Pharmacy Act to remove the requirement that the practitioner be notified of a substitution of dosage form when the patient consents and the product substituted contains the identical amount of the drug, is not an enteric-coated or timed release product, and does not alter the desired clinical outcomes. Suggested language to implement this change is as follows.

9. PASSED IN SECTION 32 OF SB 869.

Nondisclosure Orders—Amend section 411.081 of the Government Code to add the Board of Pharmacy to a long list of agencies that are authorized to receive nondisclosure orders.

10. PASSED IN SECTION 15 OF SB 869.

Pharmacists Grounds for Discipline—Amend Section 565.001 of the Pharmacy Act as follows:

- A. Amend Section 565.001(a)(16) of the Pharmacy Act to match the language in the Grounds for Discipline of a Pharmacy Technician in Section 568.003(a)(13) so that the Board could take action on a pharmacist's license or application if the person's licensed as another health care professional (e.g. dentist or physician) has been disciplined; and
- B. Add a new paragraph (21) to allow the Board to take action on a pharmacist license if the applicant has been convicted of an offense that requires registration as a sex offender. This language is currently in Section 568.003(a)(12) and the grounds for discipline of a pharmacy technician.
- C. Amend Section 565.001(a)(4) to insert the words "or could" so that the paragraph allows the board to discipline a pharmacist who has developed an incapacity that prevents "or could" prevent to person from practicing.

11. PASSED IN SECTION 21 OF SB 869.

Continuing Jurisdiction after Expiration Date of Registration—Amend the Texas Pharmacy Act to provide for continued jurisdiction over pharmacy technicians/trainees with pending investigations beyond the date of expiration of the registration. (Note: The Act currently allows this for pharmacists and pharmacies).

Background

The Texas Pharmacy Act currently provides for continued jurisdiction over pharmacist and pharmacies that have pending investigations beyond the date of the expiration of the license. This provision is not currently provided for pharmacy technicians and pharmacy technician trainees. Because the agency does not have jurisdiction over the expired registrations, the agency cannot take action on violations. This forces the agency to maintain the evidence in case the pharmacy technician/trainee renews the registration or applies for a new registration. If this occurs sometime after the violation, the case is dated and harder to prove since witnesses may not be available.

12. **PASSED IN SECTION 8 OF SB 869.**

Disciplinary Grounds and Sanctions for Interns – Amend the Texas Pharmacy Act to allow for a greater range of disciplinary sanctions, such as reprimand, administrative penalty, or probation, similar to the sanctions allowed for other licensees. This change allows the Board to discipline a pharmacist intern for minor violations without either restricting the internship or denying the ability to participate in the internship completely.

Background

The Pharmacy Act Section 557.004 allows the Board to deny, restrict, suspend, or revoke a pharmacist intern's registration based on a violation of the Pharmacy Act. This scheme gives the Board little flexibility to allow an intern to begin an internship, but still impose some type of less severe disciplinary action for minor violations of the law.

13. **PASSED IN SECTION 28 OF SB 869.**

Notification of Address Change – Amend the Texas Pharmacy Act to require interns and pharmacy technicians/trainees to notify the Board of a change of address, name and employment.

Background

The Pharmacy Act requires pharmacists and pharmacy interns to notify the Board within 10 days of a change of address, name or employment. No such provision exists for pharmacy technicians/trainees.

14. **Prescription Monitoring Program/Controlled Substance Registration** – Transfer the controlled substances prescription monitoring program and the regulation of manufacture, distribution, and dispensation of controlled substances, chemical precursors, and chemical laboratory apparatus from the Department of Public Safety to the Board of Pharmacy.

15. **Administration of Drugs** – Amend the Texas Pharmacy Act to clarify a pharmacist's authority to administer medications.

Background

The 75th Texas Legislature amended the definition of the practice of pharmacy to include the administration of an immunization or vaccination under a physician's written protocol. Section 554.004 of the Texas Pharmacy Act further specifies the conditions under which a pharmacist may administer drugs. This section is titled "Administration of Medication" and states that the Board shall specify conditions under which a pharmacist may administer medication, including an immunization and vaccination. This section was added by the 75th Legislature and the conditions listed were intended to apply to immunizations and vaccines. However, because the wording in this section applies to administration of any medication, it appears that pharmacists may not administer any medication without first complying with all of the provisions listed in the section.

Suggested Language

Sec. 554.004. Administration of **Immunizations and Vaccinations** [Medication].

(a) The board shall specify conditions under which a pharmacist may administer [medication, including] an immunization and vaccination. The conditions must ensure that:

- (1) a licensed health care provider authorized to administer the **immunization or vaccination** [medication] is not reasonably available to administer the **immunization or vaccination** [medication];
- (2) [failure to administer the medication, other than an immunization or vaccination, might result in a significant delay or interruption of a critical phase of drug therapy;]
- [(3)] the pharmacist possesses the necessary skill, education, and certification as specified by the board to administer the **immunization or vaccination** [medication];
- (3)** [(4)] within a reasonable time after administering **an immunization or vaccination** [medication], the pharmacist notifies the licensed health care provider responsible for the patient's care that the **immunization or vaccination** [medication] was administered;
- (4)** [(5)] the pharmacist may not administer **an immunization or vaccination** [medication] to a patient at the patient's residence, except at a licensed nursing home or hospital;
- (5)** [(6)] the pharmacist administers an immunization or vaccination under a physician's written protocol and meets the standards established by the board; and
- (6)** [(7)] the authority of a pharmacist to administer **an immunization or vaccination** [medication] may not be delegated

16. Grounds for Discipline of a Pharmacy – Amend the grounds for discipline for a pharmacy to include violation of Dangerous Drug Act (DDA) and Controlled Substances Act (CSA).

Background

Violation of DDA and CSA are currently grounds for discipline for pharmacists, but not included in the grounds for discipline in a pharmacy/pharmacy owner. Because of this if a pharmacy owner who is not a pharmacist violates the DDA or CSA, the Board cannot refuse to issue or discipline a pharmacy.

Suggested Language

Sec. 565.002. Applicant for or Holder of Pharmacy License.

- (a) The board may discipline an applicant for or the holder of a pharmacy license, including a Class E pharmacy license subject to Section 565.003(b), if the board finds that the applicant or license holder has:

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- (3) violated any provision of ~~[this subtitle or any rule adopted under this subtitle]~~ or that an owner or employee of a pharmacy has violated any provision of:
- (A) this subtitle or any rule adopted under this subtitle;
 - (B) Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.), or rules relating to one of those laws; or
 - (C) **Chapter 482, 485, and 486** ~~[Section 485.031, 485.032, 485.033, or 485.034,]~~ Health and Safety Code;

XXX

- (12) been responsible for a drug audit shortage; ~~[or]~~
- (13) been disciplined by the regulatory board of another state for conduct substantially equivalent to conduct described under this subsection; or
- (14) violated any pharmacy or drug statute or rule of this state, another state, or the United States.**

17. Reporting Positive Drug Screens or Incapacity – Amend the Texas Pharmacy Act to allow:

- A. employers to report a drug screen that is positive for alcohol or non-prescribed drugs when conducted by pharmacy employers with civil immunity if reported in good faith and
- B. licensees/registrants to report another licensee/registrant for any incapacity that prevents safe practice (including abuse of alcohol or drugs) with civil immunity if reported in good faith.

Background

Several years ago, a pharmacy reported a failed drug screen of a pharmacist to TSBP. After investigation, the Board entered a rehabilitation order against the pharmacist. The pharmacist sued the pharmacy for sharing this information with the Board. Staff provided testimony in support of the employer's actions and the pharmacy won the suit. Staff would like to have a provision in the Texas Pharmacy Act that requires an employer to report positive drug screen and gives the employer civil immunity if they report in good faith. In addition, the amendment would provide the same protection to licensees/registrants who report another licensee/registrant for any incapacity that prevents safe practice.

18. Pharmacy Peer Review – Amend the Texas Pharmacy Act to specify the Board has the authority to mandate pharmacy peer review (Continuous Quality Improvement) programs in pharmacies.

Background

The 76th Texas Legislature, through the passage of S.B. 780, gave pharmacists and the Board a valuable tool to use in assessing medication errors and creating safer systems. This bill was the first in the nation to set up pharmacy peer review committees. The bill specifies that a Pharmacy Peer Review Committee may be established to:

- A. Evaluate the quality of pharmacy services or the competence of pharmacists;
- B. Suggest improvements in pharmacy systems to enhance patient care; and

- C. Investigate disagreements or complaints, determine facts, and make recommendations or issue decisions in a written report.

Most importantly, this report makes the records of a pharmacy peer review committee confidential and not subject to disclosure, discovery, or subpoena. In May 2001, the Board published *Guidelines for Establishing Pharmacist Peer Review Committees* to assist pharmacists and pharmacy owners in establishing continuous quality improvement programs that include peer review. These programs should allow pharmacists to thoroughly study their dispensing/distribution systems to establish a safer system.

Since this bill became effective in September 1999, the Board has ordered pharmacies charged with dispensing errors to develop and implement a continuous quality assurance program to detect errors, to rectify errors that have occurred, and to prevent future errors. During this time period, the Board has placed this sanction on over 50 pharmacies. Information received from pharmacies that have implemented peer review programs indicates that the programs are successful in identifying problems that may lead to dispensing errors.

Recently, other states have implemented similar programs. California recently passed legislation that requires all pharmacies to establish or participate in *"a quality assurance program that documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors."*

Suggested Language

Sec. 554.051. Rulemaking: General Powers and Duties.

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- (e) If the board determines it necessary to protect the health and welfare of the citizens of this state, the board may adopt rules to require pharmacies to establish continuous quality improvement programs to prevent errors that include pharmacy peer review as outline in Subchapter C, Chapter 564 of this subtitle.

- 19. Delegation to the Executive Director** – Amend the Pharmacy Act to clarify that the Board may delegate certain duties to the Executive Director.

Background

Because of the volume of disciplinary orders entered by the agency after we began licensing pharmacy technicians, the Board has delegated certain authority to the Executive Director (e.g., entering certain types of orders (voluntary revocations, simple falsification of an application, etc). Both the Texas Medical Practices Act and the Nursing Practice Act contain specific language regarding the delegation of certain functions to the Executive Director. However, the Texas Pharmacy Act is silent on the Board's ability to delegate certain duties to the Executive Director.

- 20. Authorization for Inspections** – Expand the Board's inspection authority to include the ability to enter a pharmacy for general regulation purposes.

Background

The Pharmacy Act, Section 556.001, authorizes a representative of the Board to enter and inspect a pharmacy relating to: (1) drug storage and security, (2) equipment, (3) sanitary conditions, and (4) records, reports, or other documents required by federal and state drug laws. The authorized reasons for inspections limit the Board's ability to properly inspect and determine whether a pharmacy is truly compliant with the law and offering safe pharmacy services to the public.

Suggested Language

Sec. 556.051. Authorization To Enter and Inspect. The board or a representative of the board may enter and inspect a facility relative to the following:

- (1) drug storage and security;
- (2) equipment;
- (3) sanitary conditions; [et]

- (4) records, reports, or other documents required to be kept or made under this subtitle, Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.) or rules adopted under one of those laws; **or**
- (5) professional conduct of persons licensed or registered under this subtitle, as the conduct relates to the practice of pharmacy in accordance with this subtitle or rules adopted under this subtitle.**

Sec. 556.053. Extent of Inspection; Confidentiality. Except as otherwise provided in an inspection warrant, the person authorized to represent the board may:

- (1) inspect and copy documents, including records or reports, required to be kept or made under this subtitle, Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.) or rules adopted under one of those laws;
- (2) inspect, within reasonable limits and in a reasonable manner, a facility's storage, equipment, security, prescription drugs or devices, or records; [øf]
- (3) perform an inventory of any stock of prescription drugs or devices in a facility and obtain samples of those substances.
- (4) observe and copy records related to the professional conduct of persons licensed or registered under this subtitle as the conduct relates to the practice of pharmacy in accordance with this subtitle or rules adopted under this subtitle.**

- 21. Pharmacy Technician Training** – Amend the Pharmacy Act to require that by January 1, 2015, all new pharmacy technicians must have attended a Board Approved training program. Add a provision to grandfather persons already registered as pharmacy technicians on that date.

Background

In 2008, a Task Force was convened by TSBP to review all of the rules pertaining to Class C (Institutional) pharmacies. One of the recommendations made by the Task Force was for the Board to consider requiring that all pharmacy technicians licensed after 2015 be required to have completed a Board approved training program. The Task Force based its recommendations on a vision statement of the Joint Commission of Pharmacy Practitioners (JCPP).

Suggested Language

Sec. 568.001. Rules Relating to Pharmacy Technicians.

- (a) In establishing rules under Section 554.053(c), the board shall:
 - (1) prior to January 1, 2015, require that a pharmacy technician:**
 - (A) have a high school diploma or a high school equivalency certificate or be working to achieve an equivalent diploma or certificate; and**
 - (B) (2) have passed a board-approved pharmacy technician certification examination.**
 - (2) require that persons applying for a pharmacy technician registration on or after January 1, 2015 shall:**
 - (A) have a high school diploma or a high school equivalency certificate;**
 - (B) have completed a board-approved training program; and**
 - (C) have passed a board-approved pharmacy technician certification examination.**
- (b) The board shall adopt rules that permit a pharmacy technician to perform only nonjudgmental technical duties under the direct supervision of a pharmacist.

- 22. Pharmacist Service in Small Hospitals** – Amend the Texas Pharmacy Act to require all Class C Pharmacies (other than ASCs) to have the services of a full-time pharmacist (or alternatively, to require all Class C Pharmacies located in hospitals with more than 50 beds to have a full-time pharmacist).

Background

Since 1981, the Texas Pharmacy Act has specified that a Class C Pharmacy in a hospital with 100 beds or less is not required to have a full-time pharmacist but may employ a pharmacist on a part-time or consulting basis according to the needs of the institution. The Board believes every hospital, other than facilities such as Ambulatory Surgical Centers (ASC) should have a full-time pharmacists or the act should be amended to drop the number to 50 beds or less.

Suggested Language

Option #1

Sec. 562.101. Supervision of Pharmacy.

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- (c) A Class C pharmacy ~~[that is in an institution with more than 100 beds]~~ is required to be under the continuous on-site supervision of a pharmacist during the time the pharmacy is open for pharmacy services.
- ~~[(d) A Class C pharmacy that is in an institution with 100 beds or fewer is required to have the services of a pharmacist on a part-time or consulting basis according to the needs of the institution.]~~

Sec. 562.1011. Operation of Class C Pharmacy in Certain Rural Hospitals.

(a) In this section:

XXX

- (2) Rural hospital means a licensed hospital with **50** ~~[75]~~ beds or fewer that:
- (A) is located in a county with a population of 50,000 or less; or
- (B) has been designated by the Centers for Medicare and Medicaid Services as a critical access hospital, rural referral center, or sole community hospital.

Option #2

Sec. 562.101. Supervision of Pharmacy.

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- (c) A Class C pharmacy that is in an institution with more than **50** ~~[100]~~ beds is required to be under the continuous on-site supervision of a pharmacist during the time the pharmacy is open for pharmacy services.
- (d) A Class C pharmacy that is in an institution with **50** ~~[100]~~ beds or fewer is required to have the services of a pharmacist on a part-time or consulting basis according to the needs of the institution.

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- (A) is located in a county with a population of 50,000 or less; or
- (B) has been designated by the Centers for Medicare and Medicaid Services as a critical access hospital, rural referral center, or sole community hospital.

- 23. Licensing Procedures** – Modify Sections 558.051 and 558.101 of the Texas Pharmacy Act for pharmacists' qualifications for license and Section 568.002 for pharmacy technicians to include a provision that the applicants be in the United States legally and be legally able to work prior to issuing a license for pharmacists and pharmacy technicians.

Background

The licensure requirements currently do not contain any requirements that an applicant be in the United States legally and be legally able to work. Therefore, assuming that all other licensure requirements are met, the Board would not have grounds to refuse to issue the license.

- 24. Authority to Issue Citations** – Add a provision to the Texas Pharmacy Act to allow the Board to issue citations to licensees and registrants in certain situations without the need for a disciplinary proceeding, if agreed to by the licensee or registrant. The situations could include violations such as pharmacy technicians working with no or with an expired registration.

Background

This provision would allow for more timely resolutions of simple cases while giving the licensees the option to proceed with the usual disciplinary process. In addition, the workload on staff would be significantly decreased both in the Enforcement and Legal divisions.

25. PASSED IN SECTION 20 OF SB 869.

Requirement to be a Pharmacy Technician/Trainee – Amend the Texas Pharmacy Act, Section 568.001 of the Texas Pharmacy Act to require a pharmacy technician or pharmacy technician trainee to be of "good moral character."

Background

Currently the Texas Pharmacy Act in Section 558.051(a) specifies that a pharmacist must be of "good moral character." Staff believes that this requirement should also be added to the requirements for a pharmacy technician/trainee.

26. Costs of Investigations/Litigation – Amend the Texas Pharmacy Act to allow the Board to recover the costs of:

- A. investigations when disciplining a licensee; and
- B. litigation from licensees if successfully prosecuted at SOAH.

Background

Field investigations and litigation are very costly, especially those involving complicated issues, such as non-therapeutic dispensing. This provision would allow the Agency to collect investigative and litigation costs if the case results in discipline. The National Association of Boards of Pharmacy's Model Act and a number of other state Boards of pharmacy have these types of provisions.

27. Patient Access to Records – Amend the Texas Pharmacy Act to clarify that patients have a right to access their pharmacy records in a reasonable time and for a reasonable charge (and allow the board to define "reasonable").

28. Pharmacist Professional Discretion – Clarify that pharmacists have professional discretion when deciding to dispense a prescription or medication order.

Background

The Pharmacy Act does not specifically state that pharmacists have the discretion to refuse to fill a prescription for any professional reason such as if the pharmacist believes the prescription may present a danger to the patient. The Board has essentially interpreted the law in this manner since there is nothing to the contrary in the Pharmacy Act.

Suggested Language

Add a new Section 562.056 to the Act.

Sec. 562.056. Dispensing a Prescription. A pharmacist shall not dispense a prescription drug or medication order, if :

- (1) in the pharmacist's professional judgment, it would be harmful to the recipient; or**
- (2) the pharmacist knows or should have known that the prescription or medication order:**
 - (A) is not for a legitimate medical purpose or in the usual course of professional practice;**
 - or**
 - (B) the prescription was issued without a valid patient-practitioner relationship.**

29. 30-Day Emergency – Amend the Texas Dangerous Drug Act to incorporate authority for pharmacists to provide 30-day supply of drugs during a declared disaster.

Background

SB 1658 passed by the 2007 Texas Legislature amended the Pharmacy Act and the Texas Controlled Substances Act, to give pharmacists the authority to provide 30-days supply of prescription drugs during a declared disaster. However, this bill did not include this provision in Section 483.047 of the Texas Dangerous Drug Act.

Suggested Language

Sec. 483.047. Refilling Prescription Without Authorization.

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- (c) **Notwithstanding Subsection (b), in the event of a natural or manmade disaster, a pharmacist may dispense not more than a 30-day supply of a prescription drug, other than a controlled substance listed in Schedule II, without the authorization of the prescribing practitioner if:**
- (1) failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering;**
 - (2) the natural or manmade disaster prohibits the pharmacist from being able to contact the practitioner;**
 - (3) the governor has declared a state of disaster under Chapter 418, Government Code; and**
 - (4) the Texas State Board of Pharmacy, through its executive director, has notified pharmacies in this state that pharmacists may dispense up to a 30-day supply of a prescription drug.**
- (d) An offense under this section is a Class B misdemeanor unless it is shown on the trial of the defendant that the defendant has previously been convicted under this chapter, in which event the offense is a Class A misdemeanor.

- 30. Maintenance of Pharmacy Records** – Amend the Texas Pharmacy Act to provide for a specific record retention period for prescription records maintained by a pharmacy of a minimum of 3 years from the date of dispensing for the original prescription and 5 years for electronic records.

Background

The Pharmacy Act does not currently address any record retention periods for maintaining prescription records in the pharmacy. The Board has, however, adopted rules [e.g. Section 281.34(a) for Class A pharmacies] that require records to be maintained for a period of two years, which corresponds with the retention periods required by the Controlled Substances Act Section 481.067 (Records) and the Dangerous Drug Act Section 483.023 (Retention of Prescriptions).

A two-year time period may not be sufficient since the pharmacies are now required to report malpractice claims to TSBP. In turn, TSBP is then required to review malpractice claims if three claims are filed within five years. This investigation could result in possible disciplinary action. Without the proper dispensing records, TSBP will be unable to investigate or take disciplinary action. If a pharmacy is only required to maintain records for two years, the records required to undertake a proper investigation and disciplinary action may no longer exist.

- 31. Cancellation of License** – Return the ability to cancel a license by amending Section 565.051 of the Texas Pharmacy Act.

Background

During the 77th legislative session, the Pharmacy Act was codified under the Texas Occupations Code. In this process, the legislature removed the ability of the agency to cancel the license in a disciplinary procedure. Often, in negotiating a disciplinary action, a pharmacist would be willing to accept cancellation of his/her license and not revocation, although the effect of either is the same.

Suggested Language

Sec. 565.051. Discipline Authorized. On a determination that a ground for discipline exists under Subchapter A, or that a violation of this subtitle or a rule adopted under this subtitle has been committed by a license holder or applicant for a license or renewal of a license, the board may:

- (1) suspend the persons license;
- (2) revoke the persons license;
- (3) **cancel;**
- (4)** restrict the persons license to prohibit the person from performing certain acts or from practicing pharmacy or operating a pharmacy in a particular manner for a term and under conditions determined by the board;
- (5)** ~~[(4)]~~ impose an administrative penalty under Chapter 566;
- (6)** ~~[(5)]~~ refuse to issue or renew the persons license;
- (7)** ~~[(6)]~~ place the offenders license on probation and supervision by the board for a period determined by the board and impose a requirement that the license holder:
 - (A) report regularly to the board on matters that are the basis of the probation;

- (B) limit practice to the areas prescribed by the board;
- (C) continue or review professional education until the license holder attains a degree of skill satisfactory to the board in each area that is the basis of the probation; or
- (D) pay the board a probation fee to defray the costs of monitoring the license holder during the period of probation;
- (8)** ~~[(7)]~~ reprimand the person;
- (9)** ~~[(8)]~~ retire the persons license as provided by board rule; or
- (10)** ~~[(9)]~~ impose more than one of the sanctions listed in this subsection.

32. PASSED IN SECTION 33 OF SB 869. IN ADDITION, CHANGES TO DESIGNATE SUBTITLE J OF THE OCCUPATIONS CODE AS THE TEXAS PHARMACY ACT WERE MADE IN SECTIONS 1 AND 2 OF SB 869.

~~**Repeal of Chapter 567** – Amend the Texas Pharmacy Act to either repeal the chapter or locate the chapter in another part of the code that deals with manufacturing or repackaging, since these activities are not regulated by the Pharmacy Board.~~

~~Background~~

~~Chapter 567 of the Occupations Code imposes labeling requirements for certain prescription drugs or drug products on manufacturers, repackagers, and distributors. At one time, the Board of Pharmacy was responsible for the licensing of Manufacturers while the Department of State Health Services was responsible for the regulation of Wholesalers. This language is a holdover from those times. Currently, the Texas Department of State Health Services (DSHS) is responsible for the regulation of Manufacturers and Wholesalers. DSHS has reviewed this language and has agreed that the language needs to be deleted.~~

33. Access to Financial and Pricing Data – Amend the Pharmacy Act to allow the Board access to financial records.

34. Second Orders Against Impaired Pharmacists – Amend the Texas Pharmacy Act to allow the Board the discretion of making public a second order against a person who has a chemical, physical, or mental impairment.

35. Regulation of Wholesale Drug Distributors – Amend the Texas Food, Drug, and Cosmetic Act to transfer the authority to license and discipline wholesale drug distributors to the Pharmacy Board.

Background

The Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Subchapter I govern the licensing and disciplinary actions authorized for wholesale drug distributors. This authority is currently under the auspices of the Texas Department of Health. The Pharmacy Board regulates pharmacies and pharmacies that deal with the distribution of prescriptions drugs. If both wholesalers and pharmacies/pharmacists were regulated by one agency, that agency could more effectively handle the regulation the distribution of drugs.